MAY - 3 2012

# 510(k) Summary K113812

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| Date prepared: | May 1, 2012 | | |
| Applicant: | Atlaim Corp.<br>1018/19 Sicox Tower, Sangdaewon, Seongnam<br>Gyeonggi, 462-120 Korea | | |
| Contact person: | John Ross, General Manager, 949-929-5910 | | |
| Trade name: | ATAL 8 and ATAL 8 C | | |
| Common name: | Solid state X-ray imager | Class: | 2 |
| Classification name: | Solid state x-ray imager (flat panel/digital imager) | Product code: | MQB |
| Predicate device: | DRTech FLAATZ 750 K080064 | | |
| Device description: | The ATAL 8 and ATAL 8C are flat-panel type digital X-ray detectors that capture radiographic images in digital format within seconds, eliminating the need for an entire X-ray film or an image plate as an image capture medium. The ATAL 8 and ATAL 8C device differs from traditional X-ray systems in that, instead of exposing a film and chemically processing it to create a hard copy image, a device called a Detector Panel is used to capture the image in electronic form. Once the system captures a radiographic image and subsequently displays and stores an image, radiologists or physicians can adjust the image electronically to optimize the view of the desired anatomy at a workstation. The system enables a user to duplicate images without having to take additional exposures so that the user can easily transmit a duplicate to the second physician who needs the duplicate image through the network. The ATAL 8 and ATAL 8C differ only in the enclosure type. They have identical technological characteristics. | | |
| Intended use: | The ATAL 8 and ATAL 8C are indicated for use in general radiographic images of human anatomy. It is intended to replace radiographic film/screen systems in all general-purpose diagnostic procedures, excluding fluoroscopic, angiographic, and mammographic applications. | | |
| Technological characteristics: | Amorphous silicon detector producing an image of 3072x3072 pixels. The image area is 430x430 mm with a resolution of 3.1 lp/mm. The intended application of this detector is general radiography. | | |
| Non-clinical tests submitted or relied upon: | Non-clinical testing included performance tests, EMC tests, Electrical Safety and software validation tests. The performance testing was based on the requirements of the FDA Guidance Document for Solid State Imaging Devices and included tests for MTF, DQE, Quantum Limited Performance, Effects of Aliasing, Output Signal Level and Linearity, and Lag or residual signal level from prior exposure | | |
| Clinical tests submitted or relied upon: | Clinical image sets were obtained for both the ATAL 8 and the predicate device and they were compared to show equivalence. The clinical evaluation was performed in accordance with the FDA Guidance Document wherein 30 pairs of clinical images are acquired and a board certified Radiologist reviewed the images and declared the new panel to be equivalent or better than the predicate device, and that the images are of diagnostic quality. | | |
| Substantial equivalence conclusion: | The ATAL 8 and ATAL 8C and its predicate are different in minor details, but they are substantially equivalent with respect to intended use, technological and performance characteristics. The devices are as safe, as effective, and perform as well as or better than the legally marketed predicate device. | | |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Atlaim
% Daniel Kamm, P.e.
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Re: K113812
Trade/Device Name: ATAL 8 and ATAL 8c
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: March 22, 2012
Received: March 26, 2012

Dear Mr. Kamm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K113812

Device Name: ATAL 8 and ATAL 8c

Indications For Use:
The ATAL 8 and ATAL 8c is indicated for use in general radiographic images of human anatomy. It is intended to replace radiographic film/screen systems in all general-purpose diagnostic procedures, excluding fluoroscopic, angiographic, and mammographic applications.

Prescription Use _X_ AND/OR Over-The-Counter Use ____.
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

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(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
510K K113812